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EXAMINER
ROBINSON, HOPE A

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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In re Application of :
Van Der Berg et al :Decision on Petition
Serial No.:10/575,369 :
Filed : 11 April 2006 :
Attorney Docket No.: GRT/4662-168 :

This letter is in response to the Petition under 37 C.F.R. 1.144 and 1.181 filed on 9 November 2009 to request withdrawal of the restriction requirement mailed 4 June 2008 in view of the claims as currently pending.

BACKGROUND

This application was filed as a national stage application under 35 USC 371 and as such, is eligible for unity of invention practice.

On 4 June 2008, the examiner divided the claims into 5 Groups as follows

Group I, claims 1-9;
Group II, claims, 10-14;
Group III, Claims 15-20;
Group IV, Claims 21-25;
Group V, Claim 26

Groups I-IV were all drawn to drawn to methods for preparing a host cell while Group V was drawn to a polynucleotide. As evidence of lack of special technical feature which makes a contribution over the prior art, the examiner referred to US Patent 6,608,213.

On 8 August 2008, applicants elected, Group I, Claims 1-9 with traverse.

On 26 November 2008, the examiner mailed to applicants a non-final Office action. The examiner addressed the traversal and made the restriction requirement FINAL.

Claims 10-26 were withdrawn as being directed to non-elected invention.

Claims 1-9 were examined on the merits.

Claims 1-4 and 6-9 were rejected under 35 USC 102 as being anticipated by Wolff.

Claims 1-9 were rejected under 35 USC 102 as being anticipated by Johnson.

On 26 March 2009, applicants filed a response to the Office action, with an amendment that added new claims 27 and 28.

On 8 June 2009, the examiner mailed to applicants a second non- final Office action. The examiner indicated that claims 10-21, 23-25, and new claims 27-28 were withdrawn as being directed to non-elected invention, there being no allowable generic or linking claim.

Claims 1-9 were rejected under 35 USC 112, first paragraph for written description and for lack of enablement.

Claims 1-4 and 6-9 remained rejected under 35 USC 102 as being anticipated by Wolff.

Claims 1-9 remained rejected under 35 USC 102 as being anticipated by Johnson.

On 9 November 2009, applicant submitted the petition currently under review along with a response to the Office action and new claims 29-38.

DISCUSSION

The petition and file history have been carefully considered, with regard to the claims as currently pending in the amendment filed 9 November 2009.

Paragraph 10.01 of the ISPE Guidelines state that

> With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art.

Paragraph 10.06 of the ISPE Guidelines state that

> Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims.

In order to show unity of invention lacking between independent claims, one would need to identify technical features which are required by a first claim and not required by the second claim and then, identify technical features which are required by the second claim and not required by the first claim. An analysis for method claims would involve consideration of the method steps. The chart on the next page aligns the various limitations of the independent method claims 1, 15, 29 and 35. As shown in the chart, all four independent method claims require the same active steps of transfecting host cells with labeled polynucleotide and isolating the resulting transfected or modified host cell.

Claim 1 (examined)	Claim 15 (withdrawn Group III)	Claim 29 (new)	Claim 35 (new)
A method for preparation of a modified host cell comprising: a) transfecting host cells with at least one			
polynucleotide to which a label is covalently coupled; and	DNA which is covalently coupled to a fluorescent label that provides to the host cell a non-inheritable trait,	DNA to which a fluorescent label is covalently coupled;	
b) isolating the transfected host cell,			
	by detecting the fluorescent label and then separating fluorescent host cells which were transfected from non-fluorescent host cells which were not transfected,	b) separating transfected host cells, which contain the fluorescent label, from non-transfected host cells, which do not contain the fluorescent label, by detection of the fluorescent label;	
		and c) isolating a modified host cell from the separated and transfected host cells,	
	c) culturing the transfected host cell such that fluorescently-labeled polynucleotide integrates into the host cell's genome,		c) culturing the fluorescent label-containing host cells under proliferating conditions,
	d) multiplying the transfected host cell which has polynucleotide integrated in its genome	wherein the at least one DNA integrates into the modified host cell's genome	
	such that the fluorescent label is diluted and lost in progeny of the transfected host cell, and		Whereby the fluorescent label is diluted and lost in progeny of the fluorescent label-containing host cells; and
	e) isolating from non-labeled progeny of the transfected host cell		d) isolating a modified host cell from the cultured host cells,
Wherein said at least one polynucleotide permanently changes metabolic property of the transfected host cell	a modified host cell having a changed metabolic property.	thereby permanently changing a metabolic property of transfected host cells	Wherein a metabolic property of the modified host cell is permanently changed
as compared to the non-transfected host cell;	as compared to the host cell prior to transfection	as compared to non-transfected host cells.	
Wherein the label provides to the host cell a non-inheritable trait.	See Claim 15 step (a), "non-inheritiable trait" and step (d) "lost in progeny"		See Claim 35 step (c) "lost in progeny"

Similarly all four independent method claims recite the same outcome- wherein the transfected or modified host cell has a changed metabolic property.

While there are some differences in the scope of the limitations, these differences appear to be varying breadth or definition. For example, in place of the last clause of Claim 1 "wherein the label provides to the host cell a non-inheritable trait", Claim 15, step (d) and Claim 35, step (c) recite comparable limitations that "the fluorescent label is diluted and lost in the progeny."

With respect to the limitation of "polynucleotide," Claim 1 and Claims (15, 29 and 35) are related as genus and species. Claim 1 is generic to any polynucleotide while Claims 15, 19 and 32 require the species of DNA. It is inappropriate to require a restriction between a genus and a species. Moreover, the prior art (Wolff and Johnson) which was applied under 35 USC 102(b) teaches DNA.

With respect to the limitation of "label," Claim 1 and Claims (15, 29 and 35) are related as genus and species. Claim 1 is generic to any label while Claims 15, 19 and 32 require the species of a fluorescent label. Dependent Claim 5, which had already been examined on the merits, is limited to the same species of "fluorescent label". Moreover, the prior art (Wolff and Johnson) which was applied on Claim 4 under 35 USC 102(b) teaches fluorescent labels.

> 5. (original) A method according to claim 3, wherein the label is a fluorescent label and the means for detection is a Fluorescent Activated Cell Sorter (FACS).

The limitation of Claim 32, step (c), "culturing the fluorescent label-containing host cells under proliferating conditions," is comparable to twice-previously examined Claim 6:

> 6. (currently amended) A method according to claim 1, wherein the transfected host cell of [[step]] b) is subsequently cultured under proliferating conditions.

The limitation of Claim 32, step (b), "separating transfected host cells, which contain the fluorescent label, from non-transected host cells, which do not contain the fluorescent label is comparable to twice-previously examined Claim 2:

> 2. (original) A method according to claim 1, wherein isolation of the transfected host cell is established by direct separation of the host cells containing said label from host cells not containing said label.

For these reasons, Claims 1, 15, 29 and 35 encompass the same embodiments, and vary only in breadth or scope. Claims 1, 15, 29 and 35 share same or corresponding technical features such that unity of invention is present.

DECISION

Accordingly, the petition is **GRANTED.**

The restriction required between elected Group I, claims 1-9 and Group III, claims 15-20 and 27-28 is withdrawn.

Claims 29-38, which were newly added on 9 November 2009, will be examined with the elected invention.

The non-final Office action mailed 8 June 2009 is withdrawn as incomplete.

The application will forwarded to the examiner to consider the papers filed 9 November 2009 and to prepare an Office action on the merits on Claims 1-9, 15-20 and 27-38.

There is no fee for this petition.

Should there be any questions regarding this decision, please Quality Assurance Specialist Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-0512 or by Official Fax at 571-273-8300.

Remy Yucel
Director, Technology Center 1600